

Docket No. ORT-1436

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Virginia SMITH-SWINTOSKY, Michael RENZI, Carlos PLATA-SALAMAN, Linda JOLLIFFE, Francis FARRELL and Dana JOHNSON

Serial No.: 09/863,600 Art Unit: Not Assigned

Filed: 23 May 2001 Examiner: Not Assigned

For: **NEUROPROTECTIVE PEPTIDES**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on

29 November 2001

(Date of Deposit)

John W. Wallen, III, Esq.

(Name of applicant, assignee, or Registered Representative)

(Signature)

29 November 2001

(Date of Signature)

Assistant Commissioner for Patents  
2900 Crystal Drive  
Arlington, Virginia 22202-3550

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ORT-XXXX/JWW the fee of \$180.00 as set forth in §1.17(p).

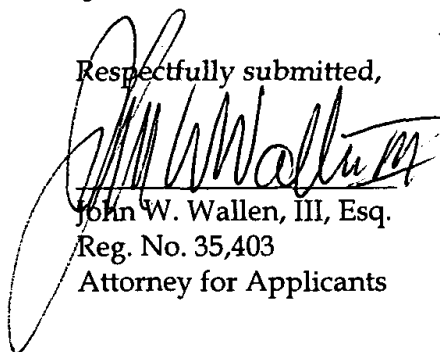
☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ORT-XXXX/JWW the fee of \$180.00 as set forth in §1.17(p).
- ☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).
- ☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
- ☒ There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

- ☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

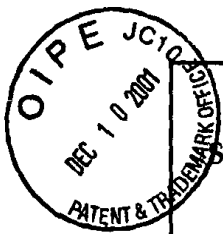
Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/ORT-1436/JWW. This form is submitted in triplicate.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John W. Wallen, III", is written over the typed name and title.

John W. Wallen, III, Esq.  
Reg. No. 35,403  
Attorney for Applicants

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, New Jersey 08933-7003  
(858) 784-3239  
DATE: 29 November 2001



SUBMISSION UNDER MPEP 609 D  Page 1 of 3	Application Number	09/863,600
	Filing Date	23 May 2001
	First Named Inventor	SMITH-SWINTOSKY
	Group Art Unit	N/A
	Examiner Name	N/A
	Attorney Docket Number	ORT-1436

### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	U.S. Patent Document		Pages, Columns, Lines, where relevant passages or relevant figures appear
			Number	Kind Code <sup>2</sup> (if known)	
			US 5,571,787		
			US 5,643,575		
			US 5,688,679		
			US 5,696,080		
			US 5,700,909		
			US 5,714,459		
			US 5,767,078		
			US 5,773,569		

### FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	Foreign Patent Document			Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
			Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>		
				EPO 640619			
				WO 94/12650			
				WO 95/03821			
				WO 99/05268			
				WO 99/11781			
				WO 99/21966			
				WO 99/38890			

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		B. S. Beckman and M. Mason-Garcia, "Signal Transduction in Erythropoiesis", <i>The FASEB Journal</i> (1991) 5(14): 2958-2964.	
		Bernaudo et al., "A Potential Role for Erythropoietin in Focal Permanent Cerebral Ischemia in Mice", <i>J. Cereb. Blood Flow Metab.</i> (1999) 19:643-51.	
		Brint et al., "Focal Brain Ischemia in the Rat: Methods for Reproducible Neocortical Infarction Using Tandem Occlusion of the Distal Middle Cerebral and Ipsilateral Common Carotid Arteries", <i>J. Cereb. Blood Flow Metab.</i> (1988) 8(4):474-485.	
		Campana et al., "Identification of a Neurotrophic Sequence of Erythropoietin", <i>Inter. J. Mol. Med.</i> (1998) 1:235-241.	
		Eschbach et al., "Correction of the Anemia of End-stage Renal Disease with Recombinant Human Erythropoietin: Results of a Combined Phase I and II Clinical Trial", <i>New Engl. J. Med.</i> (1987) 316(2): 73-78.	

Examiner Signature	Date Considered
--------------------	-----------------

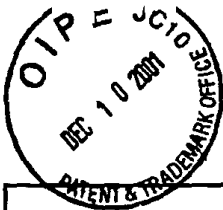


SUBMISSION UNDER MPEP 609 D  Page 2 of 3	Application Number	09/863,600
	First Named Inventor	SMITH-SWINTOSKY
	Attorney Docket Number	ORT-1436

#### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		<u>Genc</u> et al., "Erythropoietin Exerts Neuroprotection in 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridin-treated C57/BL Mice Via Increasing Nitric Oxide Production", <i>Neuroscience Letters</i> (2001) 298:139-141.	
		<u>Johnson</u> et al., "Identification of a 13 Amino Acid Peptide Mimetic of Erythropoietin and Description of Amino Acids Critical for the Mimetic Activity of EMP1", <i>Biochemistry</i> (1998) 37:3699-3710.	
		<u>Johnson</u> et al., "Amino-Terminal Dimerization of an Erythropoietin Mimetic Peptide Results in Increased Erythropoietic Activity", <i>Chemistry &amp; Biology</i> (1997) 4(12):939-950.	
		<u>Juul</u> et al., "Immunohistochemical Localization of Erythropoietin and its Receptors in the Developing Human Brain", <i>Pediatr. Dev. Pathol.</i> (1999) 2(2):148-158.	
		<u>Juul</u> et al., "Erythropoietin and Erythropoietin Receptor in the Developing Human Central Nervous System", <i>Pedr. Res.</i> (1998) 43(1):40-49.	
		<u>Juul</u> et al., "Erythropoietin in the Cerebrospinal Fluid of Neonates who Sustained CNS Injury", <i>Ped. Res.</i> (1999) 46(5):543-547.	
		<u>Konishi</u> et al., "Trophic Effect of Erythropoietin and Other Hematopoietic Factors on Central Cholinergic Neurons In Vitro and In Vivo", <i>Brain Res.</i> (1993) 609:29-35.	
		<u>Koshimura</u> et al., "Effects of Erythropoietin on Neuronal Activity", <i>J. Neurochem.</i> (1999) 72(6):2565-2572.	
		Sanford B. Krantz et al., "Erythropoietin", <i>Blood</i> (1991) 77(3): 419-434.	
		<u>Marti</u> et al., "Detection of Erythropoietin in Human Liquor: Intrinsic Erythropoietin Production in the Brain", <i>Kidney Int.</i> (1997) 51(2):416-418.	
		<u>Masuda</u> et al., "A Novel Site of Erythropoietin Production: Oxygen-Dependent Production in Cultured Rat Astrocytes", <i>J. Biol. Chem.</i> (1994) 269(30):19488-19493.	
		<u>Mattson</u> et al., "Calcium, Free Radicals and Excitotoxic Neuronal Death in Primary Cell Culture", <i>Methods Cell Biol.</i> (1994) 46:187-216.	
		<u>Morishita</u> et al., "Erythropoietin Receptor is Expressed in Rat Hippocampal and Cerebral Cortical Neurons, and Erythropoietin Prevent In Vitro Glutamate-Induced Neuronal Death", <i>Neurosci.</i> (1997) 76(1):105-116.	
		<u>Nakamura</u> et al., "Elevated Levels of Erythropoietin in Cerebrospinal Fluid of Depressed Patients", <i>Amer. J Med. Sci.</i> (1998) 315:199-201.	
		<u>Sadamoto</u> et al., "Erythropoietin Prevent Place Navigation Disability and Cortical Infarction in Rats with Permanent Occlusion of the Middle Cerebral Artery", <i>Biochem. Biophys. Res. Comm.</i> (1998) 253:26-32; Article No. RC989748.	
		<u>Sakanaka</u> et al., "In Vivo Evidence that Erythropoietin Protects Neurons from Ischemic Damage", <i>Proc. Natl. Acad. Sci.</i> (1998) 95:4635-4640.	
		<u>Silva</u> et al., "Erythropoietin Can Promote Erythroid Progenitor Survival by Repressing Apoptosis Through Bcl-XL and Bcl-2", <i>Blood</i> (1996) 88(5):1576-1582.	

Examiner Signature	Date Considered
--------------------	-----------------



<b>SUBMISSION UNDER MPEP 609 D</b>  Page 3 of 3	<i>Application Number</i>	09/863,600
	<i>First Named Inventor</i>	SMITH-SWINTOSKY
	<i>Attorney Docket Number</i>	ORT-1436

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		<u>Smith-Swintosky</u> et al., "Protease-Activated Receptor 2 (PAR-2) is Present in the Rat Hippocampus and is Associated with Neurodegeneration", <i>J. Neurochem.</i> , (1997) 69:1890-1896.	
		<u>Tabira</u> et al., "Neurotrophic Effect of Hematopoietic Cytokines on Cholinergic and Other Neurons In Vitro", <i>Int. J. Dev. Neurosci.</i> (1995) 13(3/4):241-252.	
		<u>Winearls</u> et al., "Effect of Human Erythropoietin Derived From Recombinant DNA on the Anaemia of Patients Maintained by Chronic Haemodialysis", <i>Lancet</i> (1986) 2(8517):1175-1177.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--